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10/534,293

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Fritz Magerl

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EXAMINER

SIGLER, JAY R

ART UNIT

PAPER NUMBER

3733

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/534,293	Applicant(s) MAGERL ET AL.	
	Examiner JAY R. SIGLER	Art Unit 3733	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 January 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21, 23 and 24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-21, 23, and 24 is/are rejected.
- 7) ☒ Claim(s) 17 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 11 January 2008 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Objections

1. Claim 17 are objected to because of the following informalities: "a device" should be changed to --said device-- for clarity. Appropriate correction is required.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claim 1-8, 17, 18, 21, 23, and 24 rejected under 35 U.S.C. 103(a) as being unpatentable over Barber (US 5,236,460) in view of Kuntz (US 4,349,921).

d. Claim 1 and 18: Barber teaches an implant that can be used in procedures for stiffening the vertebral column, the implant comprising an enclosed hollow body 11 which includes at least a movable open interior receptacle 23 and a movable open exterior receptacle 13, oriented toward one another and interlock (Figure 3, the two parts fit together), and are movable from a first position (Fig. 2) to a second spread apart position (Fig. 3) by inserting a filling material (Column 3, Lines 18 and 19). The implant is bean shaped (seen in Figs. 1, 5, and 6) and has a front end and rear end. The rear end includes a connection 17 for attaching an implantation instrument 55 and is adapted for connection to a device (59 and 61) used to generate a filling pressure. One of the receptacles fits within (embodied by 23 fitting into 13; within. (n.d.). *Dictionary.com Unabridged (v 1.1)*).

Retrieved February 19, 2008, from Dictionary.com website:

<http://dictionary.reference.com/browse/within>) the other of the receptacles when the receptacles are in the first position (Fig. 2).

Barber does not though specifically teach having the wedged shaped front end. Kuntz teaches a wedge shaped end 16 to facilitate insertion into the intervertebral space (refer to Abstract). It would have been obvious to someone of ordinary skill in the art at the time the invention was made to add a wedge shaped insertion end to the either of the receptacles in the invention of Barber, in view of Kuntz, in order to facilitate insertion into the intervertebral space.

e. Claim 2-8, 17, 21, 23, and 24: Barber teaches two receptacles which interlock (Figure 3, the two parts fit together); the implant can be connected to a supply hose (embodied by Figure 5 and 6, 55 is referred to as a injecting tool in Column 3, Line 5 and can be see as a flexible tube); the other end of the supply hose is adapted for connection to said device (59 and 61) used to generate a filling pressure; the implant has an opening 17, for connecting the supply hose, which is also used for attaching an instrument (55 is also used as an installation tool, Column 6, Line 66 and Column 3, Lines 11-13) used to insert the hollow body; the filling material is made of a tissue compatible, liquid (Column 3, Lines 52-54) or initially liquid phase, self-hardening material (Column 3, Lines 1-21); the hollow body is structured on one part or over an entire surface thereof (11 including 21, 31, 33, and 37 as structures); the receptacles are sealed (Column 2, Lines 24-25) with one another; the hollow body is compressed to minimum

height before implantation (Figure 2) and said device is attached (59 and 61 through 55) to the hollow body to expand the hollow body after implantation (Column 3, Lines 18-19), where 61 can be seen as a clamping screw; the receptacles are pressurized and have a form of a partial cylinder 23 and 13, whereby base and cover plates (19 and 29) are included that are slightly arched (embodied by arches of the outer edge of 19 and 20) and are positioned parallel relative to each other (Fig. 3, 19 and 29).

4. Claims 9 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Barber (U.S. Patent 5,236,460) in view of Kuntz (US 4,349,921) as applied to claim 1 above, and further in view of Strnad et al. (U.S. Patent 6,296,665).

f. Barber, in view of Kuntz, fairly suggests the claimed invention including the receptacles being adjustable to each other, but does not teach whereby the adjusting movement is limited to a certain area, which ensures a mutual overlapping of the receptacles (claim 9 of the instant application) and that this area is limited though a screw in one of the two receptacles catching in a slit in the other of the two receptacles (claim 10 of the instant application). Strnad et al. teaches a pin 118 carried by the upper portion 102 that is disposed in a slot 120 of the lower portion 106 for the purpose of preventing the upper and lower portions from becoming disconnected (col. 5, ll. 29-35), and thus the adjusting movement of the upper and lower portions is limited to a certain area that ensures a mutual overlapping of the portions. It would have been obvious to someone of ordinary skill in the art at the time the invention was made to provide

a pin, or for this purpose a screw would be functionally equivalent, to the inner body 23 and a slot, or slit, to the lower body 13 of the modified invention of Barber, in view of Kuntz and Strnad et al., in order to prevent the upper and lower portions from becoming disconnected, and thus limiting the adjusting movement and ensuring a mutual overlapping of the receptacles.

Note: The following rejection of claim 1 is based on the selection of the second choice of the alternative limitation of “inserting a filling material or **utilizing a filling material made of an elastomer**” (emphasis added). “Inserting a filling material” is taught by Barber.

5. Claims 1 and 11-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Barber (U.S. Patent 5,236,460) in view of Kuntz (US 4,349,921) as applied to claim 1 above, and further in view of Ferree (U.S. Patent 6,419,704).

g. Claim 1 and 11: Barber, in view of Kuntz, fairly suggest the claimed invention including a resin or other liquid as a filling material, but not specifically a filler being made of an elastomer (Claim 11). Ferree teaches that an implant can be filled with an elastomer, amongst other materials (Column 5, Lines 42-45), which will enable the implant to cyclically compress and expand in a manner similar to the disc material being replaced (refer to Abstract). It would have been obvious to someone of ordinary skill in the art at the time the invention was made to use an elastomer as the filling material in the modified invention of Barber, in view of Kuntz and Ferree, in order to enable the implant to cyclically compress and expand in a manner similar to the disc material being replaced.

- h. Claim 12, 13, and 14: the elastomer would at least partially fill the space (Fig. 3); the elastomer would have been fitted to an inner side wall of the hollow body (Fig. 3); the upper and bottom walls are generally planar and would have contacted the elastomer when compressed (Fig. 3).
- 6. Claims 15 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Barber (U.S. Patent 5,236,460) in view of Kuntz (US 4,349,921) and Ferree (U.S. Patent 6,419,704) as applied to claim 1 above (paragraph 5), and further in view of Powell (U.S. Patent 4,517,844).
 - i. Claim 15 and 16: Barber, in view of Kuntz and Ferree, fairly suggests the claimed invention including the desirability of the implant to cyclically compress and expand in a manner similar to the disc material being replaced and that air can be used as a filling material (col. 5, ll. 40-43), but do not suggest an air bubble or space added to the elastomer. Powell teaches that elasticity can be changed by air bubbles to a system. It would have been obvious to someone of ordinary skill in the art at the time the invention was made to add an air bubble to the filling material of the modified invention of Barber, in view of Kuntz, Ferree, and Powell, in order to change the elasticity to allow for the implant to better compress and expand in a manner similar to the disc material being replaced. Concerning claim 15, a space below the elastomer would be functionally equivalent to an air pocket, or air bubble, and thus would change the elasticity to allow for the implant to compress and expand in a manner similar to the disc material being replaced.

7. Claims 19 and 20 rejected under 35 U.S.C. 103(a) as being unpatentable over Barber (U.S. Patent 5,236,460) in view of Kuntz (US 4,349,921).

j. Barber in view of Kuntz suggests the claimed invention above except for the implant being manufactured from a metal, polymer or a composite material or using a material that would produce radiological shadows. However, metals, polymers, composite materials and materials that would produce radiological shadows are art recognized materials for implants. It would have been obvious to one having ordinary skill in the art at the time the invention was made to form the implant of a metal, polymer or a composite material or using a material that would produce radiological shadows, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

Response to Arguments

8. Applicant's arguments filed 11 January 2008 have been fully considered but they are not persuasive.

The arguments of claim one 1 moot in view of the new ground of rejection. Additionally, the term "within" is being taken as into the interior where the interior member is going into the exterior member.

Concerning claim 5, the injecting tool 55 of Barber can be seen as a tube and flexible is **capable** of being bent, usually without breaking (flexible. (n.d.).

Dictionary.com Unabridged (v 1.1). Retrieved February 19, 2008, from Dictionary.com

website: <http://dictionary.reference.com/browse/flexible>). While the flexibility of the injection tool of Barber is not disclosed, it would be capable of being bent at least at a very small degree. Note that the instant claim does not limit the flexibility of the supply hose. Additionally, the injection tool is considered a functional equivalent since the supply hose of the claimed invention is included to deliver the filling material, which is the function of the injection tool.

Concerning claim 21, the claim does not specify in which plane the base and cover plates are arched. The base and cover plates of Barber are arched on the edges.

Concerning claim 9 and 10, while Strnad et al. does not specifically teach two receptacles, Strnad et al. does teach two telescoping members, one with a pin and one with a slot. The pin and slot are used to prevent the members from becoming disconnected (col. 5, ll. 29-35). Barber teaches the two receptacles and Strnad et al. would suggest to one skilled in the art to include a pin on one member, i.e. one receptacle of Barber, and a slot on another member, i.e. the other receptacle of Barber, to prevent them from becoming disconnected.

Concerning claim 15 and 16, Powell is considered in the field of applicants endeavor because it is in the medical art. Additionally, Powell states that the elasticity refers to the stiffness of the system and that the elasticity can be changed by air bubbles. While this does not specifically apply to the compression of an implant, it does generally apply to changing the elasticity of a material. Ferree already has been shown to suggest that it is desirable to enable the implant to cyclically compress and expand in

a manner similar to the disc material being replaced, which could be achieved using air bubbles, as suggested by Powell.

Concerning claims 19 and 20, the general teaching of *In re Leshin* is that the selection of a known material to make an invention of a type made of said known material prior to the invention is obvious (MPEP 2144.07). Generally medical implants, and more specifically spinal implants, were known in the art to be made of metals, polymers or composite materials. Adding elements to produce radiological shadows in a polymer or composite was also known (see US 6,149,704; col. 8, ll. 22-30).

Conclusion

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JAY R. SIGLER whose telephone number is (571)270-3647. The examiner can normally be reached on Monday through Thursday from 8 AM to 4 PM (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on (571) 272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/JRS/

/Eduardo C. Robert/
Supervisory Patent Examiner, Art Unit 3733